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Skin and Adhesive Issues With Continuous Glucose Monitors: A Sticky Situation

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Abstract

Background: The purpose of this article is to describe challenges associated with successful use of continuous glucose monitoring (CGM) by young children with type 1 diabetes (T1D) and to detail the techniques and products used to improve the duration of sensor wear.

Methods: The DirecNet Study Group conducted 2 studies in 169 children with T1D between the ages of 1 and 9 years who were instructed to wear a CGM device daily. Problems related to skin irritation and sensor adhesiveness in these young children presented challenges to daily use of the CGM. Study coordinators instituted a variety of techniques using commercially available products to attempt to overcome these problems.

Results: Three primary factors that contributed to reduced CGM use were identified: the limited body surface area in smaller children, ambient temperature and humidity, as well as the type and duration of physical activity. Using supplemental products to minimize the impact of these factors resulted in improved adherence and reduced skin irritation.

Conclusion: Achieving satisfactory adhesion of the CGM sensor and transmitter may involve finding the right supplemental product or combination of products through trial and error. Optimizing adhesion and minimizing skin irritation can significantly improve duration of use and tolerability of CGM devices by young children.

Keywords

CGM, adhesive, irritation, children

While the benefits of near-normalization of blood glucose levels are well established, the ability to achieve optimal glycemic control is limited by an increased risk of both mild and severe hypoglycemia.[1-5] This is particularly difficult in young children with type 1 diabetes (T1D) due to a number of factors that contribute to inadequate glycemic control including nonphysiologic insulin delivery, irregular patterns of eating and activity, insulin sensitivity, inability to recognize hypoglycemia, and parental fear of severe hypoglycemia. Unpredictable glycemic excursions are a hallmark of T1D in young children.

The use of real-time continuous glucose monitoring (CGM) systems in young children with T1D has the potential for improving glycemic control by identifying glycemic trends and excursions. CGM devices provide parents, caregivers and health care professionals a continuous display of glucose data. They provide information on the rate at which the glucose level is increasing or decreasing, as well as invaluable predictive warnings when the glucose levels are approaching the upper or lower limits of the target range. CGM technology provides real-time glucose information in response to daily carbohydrate consumption, exercise and insulin administration. The manufacturers of the CGM devices provide software that generates comprehensive reports regarding glucose trends over several days in response to insulin, activity, and carbohydrate intake. Although CGM wear alone has not been associated with consistently improved glycemic control in children, retrospective analyses of sensor glucose profiles can assist parents and caregivers in making confident insulin dose adjustments.[6]

Despite the knowledge that can be gained through the use of CGM, the Juvenile Diabetes Research Foundation (JDRF) CGM Study Group reported that consistent, nearly daily use of CGM devices in 8- to 24-year-olds was difficult to achieve.[7] We encountered similar challenges in the Diabetes Research

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in Children Network (DirecNet) CGM studies in children < 10 years of age with T1D due, in part, to the challenges involved in using these devices.[8,9] Here we describe some of the skin and adhesive problems associated with use of CGM devices in young children and the techniques and products used to overcome these obstacles that limit regular CGM use in this population.

Methods

The DirecNet Study Group conducted 2 CGM studies in 169 children with T1D between the ages of 1 and 9 years. Both protocols were approved by the institutional review boards of the 5 participating sites. Written informed consent was obtained from the parents/guardians and the child's assent was obtained when appropriate. The randomized controlled trial study is listed on www.clinicaltrials.gov (NCT00760526).[8]

Details of these studies have been reported elsewhere.[8,9] Both studies utilized the FreeStyle Navigator® 1.5 Continuous Glucose Monitoring System (Abbott Diabetes Care, Inc, Alameda, CA, USA) and the Paradigm® insulin pump with MiniLink transmitter and Sof-sensor CGM system (Medtronic MiniMed, Inc, Northridge, CA, USA). Parents of participants were trained and provided with detailed verbal and written instructions on how to wear and use the CGM device. A variety of skin and adhesive issues occurred during the study resulting in a need for supplemental products to keep the CGM sensors and transmitters adhered to the skin and to minimize irritation.

Results

Adhesive and Skin Issues

Study participants were instructed to wear the CGM device daily. While compliance was generally good, problems with skin irritation and difficulties keeping the sensor/transmitter attached limited successful CGM use in many participants. The 3 primary factors that contributed to problems with CGM use were the limited body surface area in young children, the ambient temperature and humidity level, and the types and duration of physical activity.

Device adhesive issues included transmitter and sensor fall-offs, accidental pull-offs, and transmitters becoming uncoupled from the sensor. A number of skin rashes were reported related to the CGM adhesive, other adhesive products, and plastic or nickel parts of the sensor, support mount, and/or transmitter. Bleeding at the sensor insertion site was also reported.

Contributing Factors

Body Surface Area. The studies consisted of a 1- to 2-week run-in period of masked CGM wear to assess the participant's willingness and ability to wear the CGM device. The participants wore the FreeStyle Navigator 1.5 CGM up to 5 days and the MiniMed MiniLink transmitter and Sof-sensor CGM up to 6 days per protocol during the run-in period. The participants were required to attain a total of 96 hours of CGM wear within the run-in period to proceed with participation in the study. In this young age group, the availability of adequate sites for sensor placement was limited by body surface area. The size of the sensor and transmitter limited the area in which the device could be placed so it fit comfortably and lay flat against the skin. Avoiding areas where the sensor and transmitter did not lay flat was necessary to reduce the chance of the adhesive pulling off and/or lifting of the sensor out of the skin. Participants who were also using an insulin pump had even fewer available sites for sensor placement. During the summer months, sunburned skin further limited the areas available for sensor insertions.

The upper buttocks region was used successfully by the older participants but was avoided in participants who were not yet toilet trained to avoid irritation and contamination of the sensor insertion area. The abdomen, upper arm, upper buttock, and upper thigh region were frequently used because these areas supported the devices effectively and provided a flat surface for better adhesion. Some participants avoided wearing the sensor in locations that were visible to others because they did not want unsolicited questions or comments. In contrast, some participants wore the CGM in a conspicuous area to prompt peers to ask questions about the device.

Environmental Variation. Ambient temperature and humidity level had an impact on successful use of the CGM. Hot, humid climates presented a challenge as perspiration accumulated under the sensor adhesive causing it to loosen and allowing the sensor and support mount to lift from the skin. This resulted in inadequate transmission of sensor data to the CGM receiver. High temperatures and humidity also contributed to heat rash and skin irritation.

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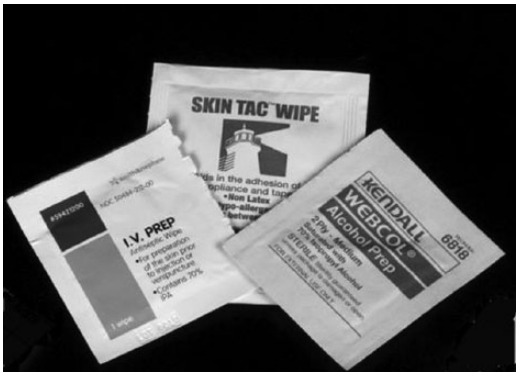

Figure 1. Adhesive wipes IV Prep and Skin Tac.

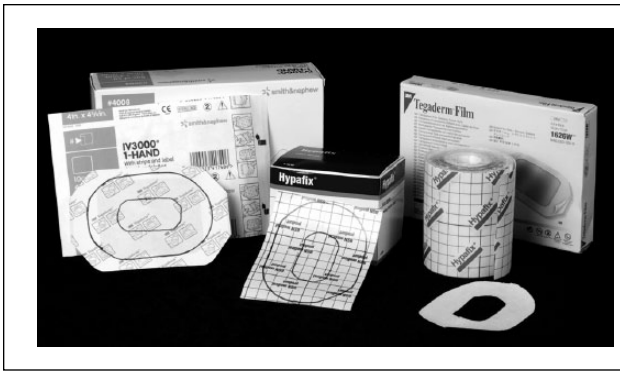

Figure 2. Transparent dressings and barriers.

Physical/Recreational Activity. Young children are usually very active both in recreational sports and general play. The physical activity of the participants posed challenges for securing the sensor to the skin and avoiding locations that would come in direct contact with other players and/or equipment used in the recreational activity. Assessing the type and level of physical activity that participants were involved in helped determine the appropriate sensor location and the need for additional products to secure and protect the sensor/transmitter.

Swimming and water sports posed additional obstacles to successfully achieving adhesion of the sensor. Prolonged water exposure caused weakening of the sensor adhesive allowing water to seep under the adhesive and cause the sensor to lift off the skin. A combination of water resistant wraps, tapes and adhesive products were used in an attempt to keep the device on the skin during these activities.

Products and Techniques to Optimize CGM Usage

While product preference varied slightly among the 5 clinical centers, it was typical to initially use as few additional adhesive products as possible to avoid skin irritation and enhance comfort. In participants who had difficulty keeping the sensor on, it was necessary to systematically institute the use of supplementary adhesive products and external wraps to help secure the sensor to the skin. These products were used alone or, in most cases, in combination to assist in keeping the sensor secured to the skin.

Liquid Adhesives. Mastisol® (Ferndale Laboratories, Inc, Ferndale, MI, USA) is a clear, latex-free, non-water-soluble liquid that is available in both bottles and single-use vials. Mastisol was applied to clean, dry skin and allowed to dry completely prior to insertion of the CGM sensor. Care was taken to avoid applying Mastisol to the area where the sensor enters the skin, creating a small area free of the liquid adhesive in which to insert the sensor. Application of Mastisol was effective in maintaining sensor adhesion in most children involved in recreational sports and water activities.

Adhesive Wipes. IV Prep® (Smith & Nephew, St. Petersburg, FL, USA) and Skin Tac™ (Torbot Group, Inc, Cranston, RI, USA) (Figure 1) are hypo-allergenic, latex-free skin barriers that clean the skin and leave a tacky residue that improves adherence of the sensor adhesive tape to the skin. These wipes were well tolerated with very few allergic reactions observed. They were frequently used in conjunction with additional transparent dressings or tapes. The wipes were used around the area where the sensor adhesive would be in contact with the skin. Care was taken to avoid applying the wipes to the area where the sensor enters the skin. After the skin dried completely, the sensor was inserted.

Transparent Dressings and Barriers. Transparent dressings (Figure 2) and film barrier products such as Tegaderm™ (Smith & Nephew, St. Paul, MN, USA), Cavilon® (3M, St. Paul, MN, USA), OpSite Flexigrid® (Smith & Nephew, St. Petersburg, FL, USA), and Bard® (C.R. Bard, Inc, Covington, GA, USA) were used when an allergic reaction to the adhesive or skin irritation from the plastic or metal components of the sensor/transmitter unit occurred. The transparent dressing or film barrier was placed on the skin prior to sensor insertion so that the sensor adhesive tape or device components did not come in direct contact with the skin. This technique was also effective in reducing skin trauma and irritation associated with sensor removal. The transparent dressings were cut in templates to optimize adhesion while limiting exposure to excessive adhesive products (Figures 3a and 3b) and were frequently used to secure the sensor/transmitter to the skin.

Two sizes of Tegaderm were utilized. The small size, 2 $^{3}/_{8}$ × 2 ¾ in (6 cm × 7 cm), was cut in half to secure the sensor (Figures 3a and 3b). The large size, 4 in × 4 ¾ in (10 cm × 12cm), was used to augment the existing CGM adhesive or to cover entire sensor/transmitter system (Figure 3b).

OpSite Flexigrid is a transparent adhesive film, with a unique grid printed on the backing. It is a comfortable, moisture-vapor-permeable film that can be left in place for up to 7 days without skin maceration.

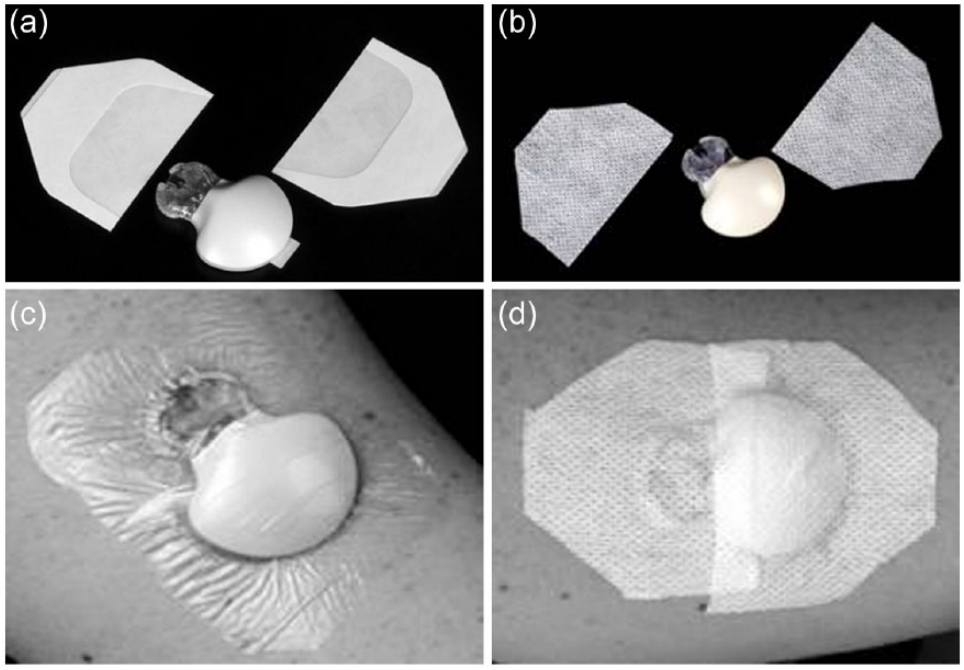

Figure 3. (a) Small Tegaderm cut in half to secure the MiniLink transmitter and Sof-sensor. (b) With the use of the small Tegaderm as a template, the Hypafix tape is cut to the small Tegaderm shape and then cut in half to secure the MiniLink transmitter and Sof-sensor with minimal adhesive exposure. (c) Application of the small Tegaderm over the Sof-sensor and MiniLink transmitter. An additional piece of Tegederm is placed under the MiniLink transmitter for participants experiencing skin irritation related to the plastic MiniLink transmitter. (d) Application of the Hypafix tape cut to secure the MiniLink transmitter and Sof-sensor.

Hypafix® (Smith & Nephew, St. Petersburg, FL, USA) is an adhesive, nonwoven fabric tape that is water resistant with a nonirritating adhesive. The tape is permeable to both air and moisture, helping to reduce the risk of maceration. It was highly conformable to uneven areas.

External Wraps. Coban® (Andover Healthcare, Inc, Salisbury, MA, USA) (Figure 4a) and other prewrap products are self-adherent elastic wraps that are typically used under athletic tape, eliminating problems with tape-related contact dermatitis and skin irritation. These products were ideal for use with CGM devices when the sensor was placed on an extremity, usually the upper arm or thigh. The wrap was placed over the sensor/transmitter unit circling the extremity 1-2 times to secure the device to the skin without the use of additional adhesive tape (Figures 4b and 4c). The wraps come in bright colors and patterns that appeal to children. In addition, Coban was frequently used as a water barrier when the participants were swimming, during play, or during recreational activities to help keep the sensor and transmitter from falling off or being accidentally knocked off during the activity.

Tapes. In children who were particularly sensitive to standard adhesive tape (paper, silk), Hy-Tape® (Hy-Tape International, Inc, Patterson, NY, USA) (latex-free, zinc-oxide-based) and Hypafix (flexible, nonwoven retention tape) were used to secure the transmitter to the sensor to prevent the transmitter from detaching from the sensor mount. These products were also used successfully when transparent dressings were not effective in keeping the CGM sensor and/or transmitter attached. Both Hy-Tape and Hypafix reportedly caused less skin trauma when removing the tape.

Protective Sleeves. For some children who could not tolerate any of the above products, a protective sleeve was used to protect and secure the sensor/transmitter unit, usually to the upper arm. The type of sleeves used included terry cloth sport wrist bands, compression sleeves, or the cuff of a small sock. As with the prewrap products, the wrist bands and sock cuffs appealed to these young participants because they were available in many colors and patterns.

Templates. Covering the entire sensor/transmitter unit with a large, solid piece of transparent dressing leads to moisture buildup under the dressing. This undermined its function to secure the sensor to the skin and increased the risk for skin irritation. To minimize this problem, the dressing was cut using the sensor/transmitter outline as a template so that the dressing only covered the sensor adhesive area and not the transmitter itself (Figure 5a-c). This also helped prevent pulling and traction on the transmitter, which could cause the sensor to back out of the insertion site resulting in sensor instability,

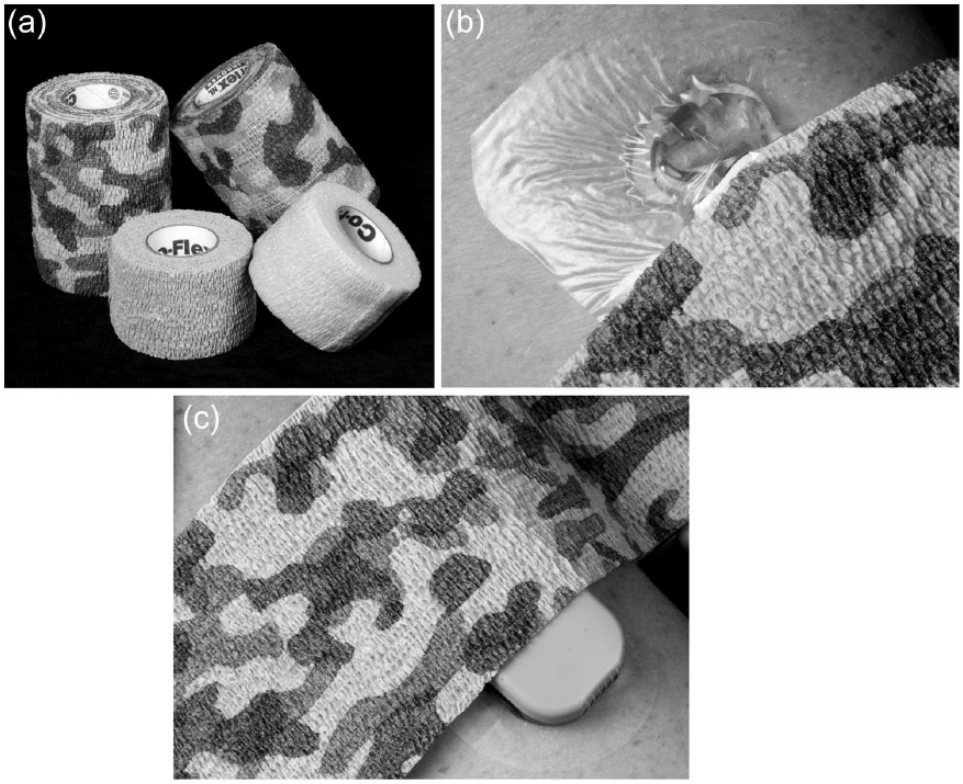

Figure 4. (a) Coban wrap in 3-in and 1.5-in widths. (b) Application of Coban to MiniLink transmitter and Sof-sensor. (c) Application of Coban to the Navigator sensor support mount and attached transmitter.

inaccurate glucose readings, and communication errors between the sensor/transmitter unit and the CGM receiver.

Site Rotation. To prevent rashes and dry skin due to the frequent application and removal of sensor adhesive and supplemental adhesive products, participants were instructed to rotate sensor insertion sites. In addition, placing a sensor in the same location repeatedly can cause superficial scarring at the insertion site, which could negatively affect the accuracy of the sensor readings.

Adhesive Remover. When necessary to make sensor removal less traumatic for both the participant and the participant's skin, adhesive removers, such as Uni-Solve® wipes (Smith & Nephew Inc, St. Petersburg, FL, USA) or Detachol® (Ferndale Laboratories, Inc, Ferndale, MI, USA), were used. Adhesive removers had to be applied carefully to avoid direct contact with the transmitter that could compromise its integrity. Using adhesive remover also helped prevent rashes and dry skin, especially in overused areas.

Discussion

Maintaining sensor/transmitter adhesion is critical for successful use of CGM devices. Replacing a sensor before the recommended duration of use is expensive and can be quite stressful for young children. Achieving satisfactory adhesion of the CGM sensor to the skin through a trial and error process to find the right combination of supplemental products (liquid adhesive, adhesive wipes, transparent dressings, tape, and wraps) can greatly improve successful CGM wear and acceptance in young patients with diabetes. The choice of adhesive products is highly individualized and must take into consideration cost as well as the impact of seasonal temperature variations and activities, such as sports and swimming.

Conclusion

Experience was gained with each adhesive issue and the use of supplemental products narrowed to allow for successful CGM use for most subjects. Despite the skin and adhesive challenges that occurred throughout the studies, the parents/caregivers were willing to work through these issues to benefit from the information CGM technology provided. Overall, the CGM was well liked by parents who were in charge of the day-to-day management of the device as indicated by responses to a CGM Satisfaction Questionnaire completed by the parents in the studies.[8,9]

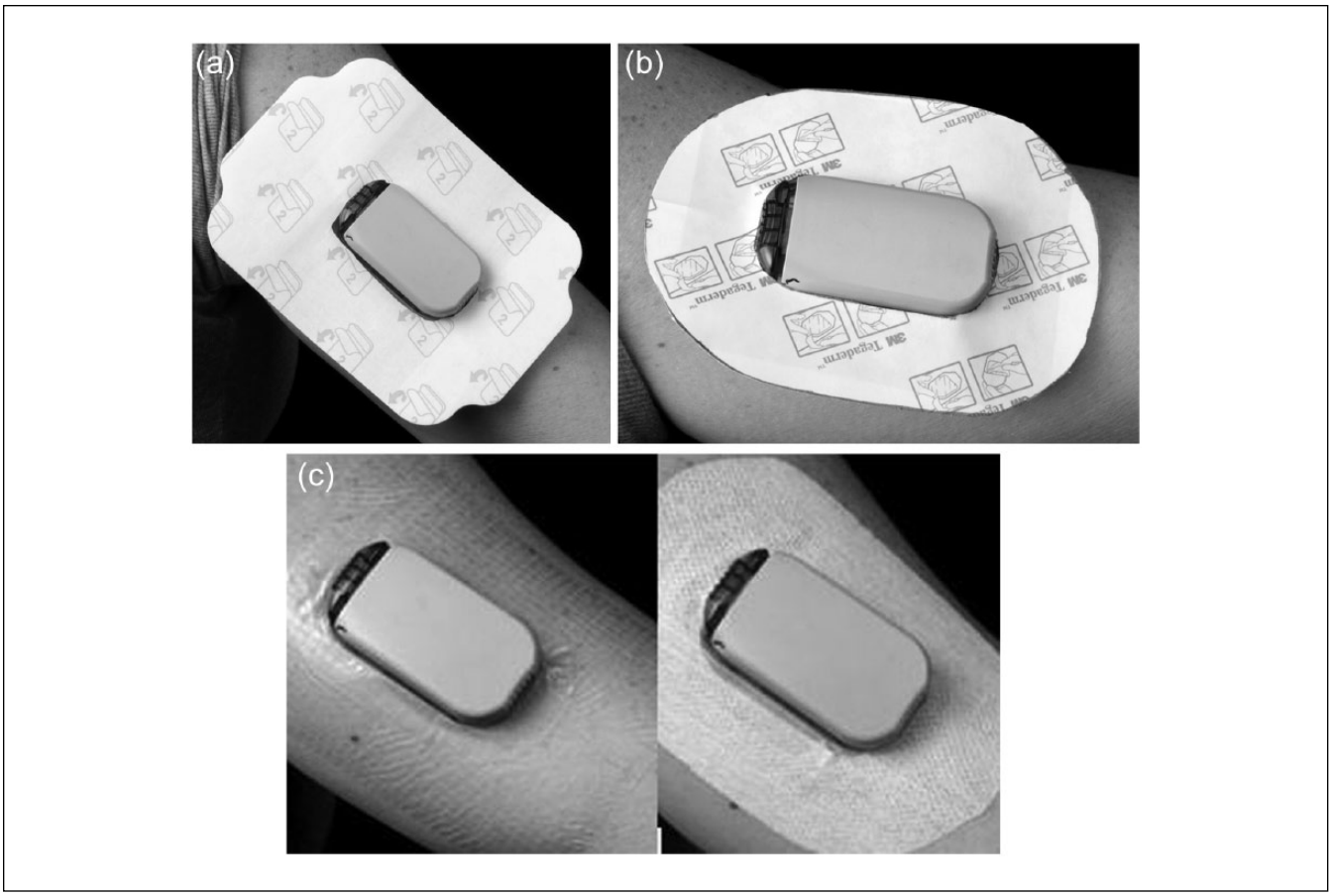

Figure 5. (a) Navigator sensor support mount/transmitter with large Tegaderm template. (b) Navigator sensor support mount/transmitter with Hypafix template. (c) Application of large Tegaderm and Hypafix respectively to the Navigator sensor support mount and transmitter.

Abbreviations

CGM, continuous glucose monitoring; JDRF, Juvenile Diabetes Research Foundation; T1D, type 1 diabetes.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: KE reports a consulting agreement with Abbott Diabetes Care, Inc, from 2009 to 2010. The other authors report no conflicts of interest.

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